



**Kao Corporation
Performance Chemicals Research Laboratories**

October 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments of Kao Corporation on Surgeon's and Patient Examination Gloves;
Reclassification: Proposed Rule (Docket No. 98N-0313)

Dear Sir/Madam:

Kao Corporation ("Kao") submits this comment in response to the Food and Drug Administration's ("FDA's") issuance of a proposed rule to reclassify surgeon's and patient examination gloves. 64 Fed. Reg. 41710 (July 30, 1999). Kao, which is headquartered in Tokyo, Japan, is a major manufacturer of food components and chemical products used in a wide variety of applications regulated in the U.S. by FDA.

Kao understands that the FDA is proposing to reclassify all surgeon's and patient examination gloves as Class II because of concerns that general controls applicable to Class I devices are insufficient to provide a reasonable assurance of safety and effectiveness. Kao further is aware that the Agency has issued a proposed guidance document, "Medical Glove Guidance Manual," which sets forth recommended protein and glove powder limits. Specifically, in this draft guidance, the FDA has recommended that natural rubber gloves contain no more than



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120 mg powder and 1,200 μ g extractable protein per glove, as measured by the ASTM D 5712 modified Lowry method. The proposed rule will require that glove labeling state this recommendation along with the actual measured amount of extractable protein per glove. 64
Fed. Reg. 41710, 41743 (July 30, 1999).

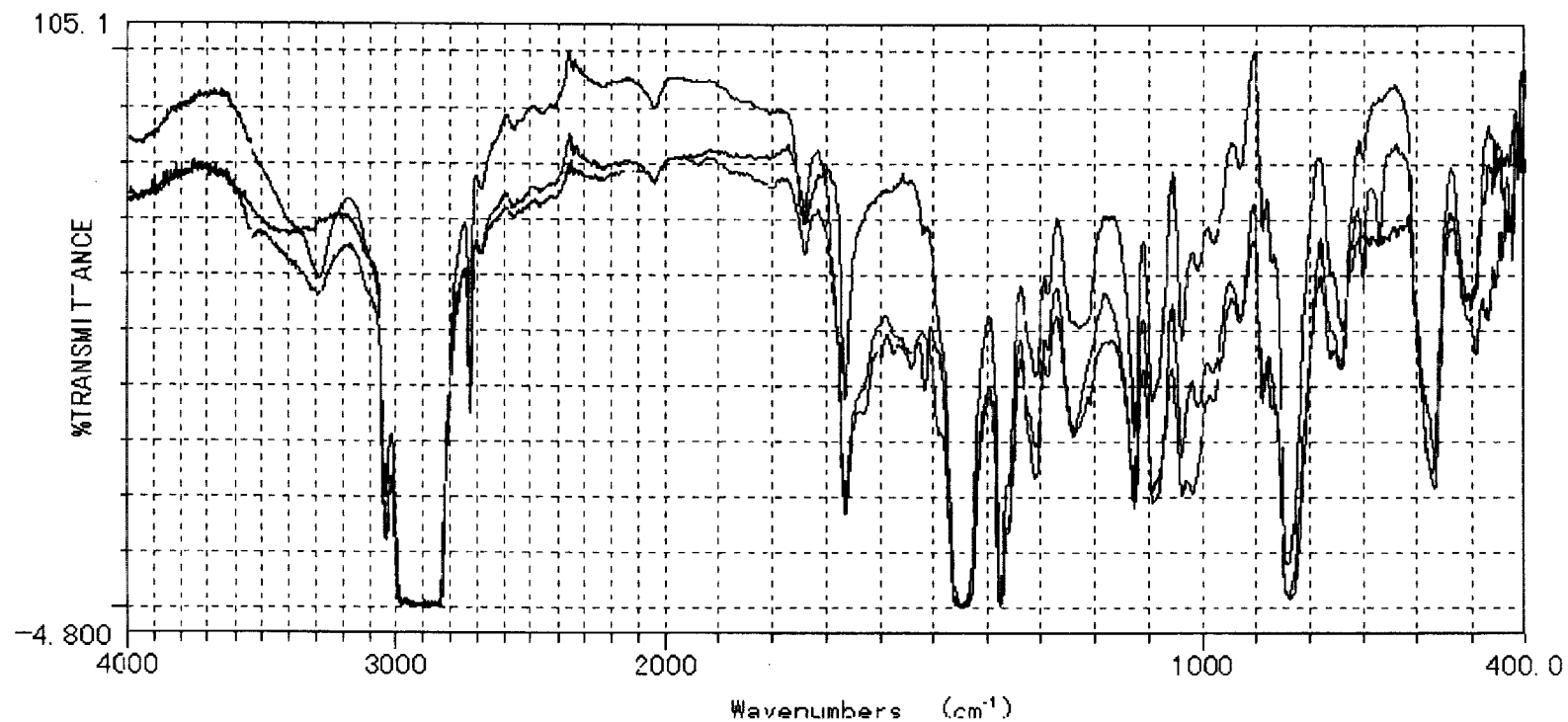
Kao has been engaged in the research and development of natural rubber latex that is able to reduce latex allergy, and has developed a highly purified natural rubber latex (Deproteinized Natural Rubber or DPNR) latex and DPNR gloves, which are able to provide significant protection against latex allergy. Kao wishes to introduce to FDA information on DPNR latex and DPNR gloves.

Sincerely,

Hiroyasu Togashi
Senior Research Chemist

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640-8505 Japan

cc: M. Elizabeth Bierman, Esq.
Morgan, Lewis & Bockius, LLP
Washington, D.C.



ファイル名 :
 タイトル :
 測定日時 : 1993年07月08日 11時17分43秒
 測定分解能 : 4 cm⁻¹
 スキャン回数 : 1 回
 測定ゲイン :
 コメント : Blue - DPNR gloves :EP content(per glove) 1200 µ g or less
 Red - Natural rubber gloves :EP content(per glove) 1200 µ g or more
 Green - Natural rubber gloves :EP content(per glove) 1200 µ g or less